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Chief Executive Officer

June 16, 2008

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To: Supervisor Yvonne B. Burke, Chair
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From: William T Fujioka
Chief Executive Officer

MOTION TO OPPOSE SB 1096 (CALDERON) RELATED TO AMENDING THE CALIFORNIA MEDICAL INFORMATION ACT (ITEM NO. 76-C, AGENDA OF JUNE 17, 2008)

Item No. 76-C, on the June 17, 2008 Agenda, is a motion by Supervisor Antonovich to oppose SB 1096 (Calderon) and send a five-signature letter opposing SB 1096 to the Governor and the members of the California State Senate and Assembly. Opposition to this measure is a matter for Board policy determination.

Existing Law

Existing Federal law, the Health Insurance Portability and Accountability Act (HIPAA), precludes health care entities from using or disclosing a patient's medical information for marketing without prior authorization from the patient. Similarly, existing State law, the Confidentiality of Medical Information Act (CMIA), prohibits any health care provider from intentionally sharing, selling, using for marketing, or otherwise using any medical information for any purpose not necessary to provide health care services to the patient, except when expressly authorized by a patient, or otherwise authorized by law.

Provisions of SB 1096

SB 1096, as amended on May 23, 2008, would add a provision to the California Medical Information Act to allow pharmacies to send written communication containing information on specified prescribed medications to patients, without prior authorization, and would deem that communication necessary to provide health care services to the patient, only when the following conditions are met:

- The written communication: a) encourages the patient to adhere to the prescribed course of medical treatment and may include information about the particular prescribed pharmaceutical drug; b) is written in the same language as the prescription label produced by the pharmacy; c) instructs the patient to contact the physician with questions about the medication, adverse affects, dosing requirements or other causes; and d) pertains only to the prescribed course of medical treatment and does not mention any other pharmaceutical products and is limited to medications prescribed for specified diseases;
- Further communication ceases when no refills remain on the prescribed medication or the pharmacy has been notified by a health care provider that a prescribed course of therapy has been discontinued or substituted with a different drug;
- All product information is consistent with the current Federal Food and Drug Administration (FDA) approved insert information and a copy of each written communication is transmitted to the FDA Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communications prior to program implementation;
- All personally identifiable medical information collected, used, and disclosed is confidential and used solely to deliver the written communication to the patient and Access to any information is limited to authorized persons that must comply with existing requirements related to patient confidentiality and security information;
- If the written communication is paid for, in whole or in part, by a manufacturer, distributor, or provider of a health care product or service, the written communication must disclose whether the pharmacy receives direct or indirect remuneration; and,
- A pharmacy shall offer the patient an opportunity to opt out of receiving the written notice at the time the initial prescription is filled or when the patient picks up the prescription. If the patient does not opt out, the written communication shall include instructions describing how the patient may opt out of receiving future notices.

According to the Senate analysis of SB 1096, the California Medical Association (CMA), which opposes the legislation, indicates that it would allow "unfettered direct marketing to consumers of pharmaceutical and health information using patients' confidential medical information." In addition, CMA noted that "this concept will interfere with the physician-patient relationship and could lead to misinformation and confusion for patients, as well as increased health costs through the direct-mail promotion of drugs."

Impact on the County

The Department of Health Services (DHS) is concerned that SB 1096 could result in direct marketing to patients and the "opt out" process is not an affirmative process to obtain the patient's consent as would be the case with an "opt in" process. CMA noted this similar concern. However, DHS indicates that the bill could benefit patients by establishing a system to notify them of needed refills with the goal of helping them maintain compliance with a prescribed course of pharmacological treatment. Since DHS operates closed pharmacies which only serve their clients, the Department does not believe SB 1096 would impact DHS-operated pharmacies. Therefore, DHS does not have a position on SB 1096.

County Counsel opines that SB 1096 is not inconsistent with provisions of Federal law in HIPPA regarding the use and disclosure of protected patient information and would modify the State CMIA which allows the sharing of patient information to third parties under specified conditions.

Because there is no Board policy to oppose legislation which would allow retail pharmacies to send written communications on prescribed medications to patients, opposition to SB 1096 is a matter for Board policy determination.

Proponents and Opponents

SB 1096 is sponsored by Adheris (a vendor that provides direct patient educational programs) and supported by the Alliance for Better Medicine, American Russian Medical Association, California Council of Community Mental Health Agencies, California Retailers Association, Community Life Improvement Program, Charles R. Drew University of Medicine and Science, Los Angeles Society of Allergy, Asthma & Clinical Immunology, Mental Health Association in California, National Association of Cancer Patients, National Consumers League, National Association of Chain Drug Stores, and Rite Aid.

The bill is opposed by the American Civil Liberties Union, California Alliance for Retired Americans, California Medical Association, Consumer Federation of California, Consumer Watchdog, Consumers Union, Privacy Rights Clearing House, and the California Pharmacists Association. SB 1096 passed the Senate on May 29, 2008 by a vote of 21 to 16. The bill is scheduled for a hearing in the Assembly Health Committee on June 17, 2008.

WTF:GK
MAL:DD:mp

c: Executive Officer, Board of Supervisors
County Counsel
Department of Health Services